

Certificate of Analysis

Argenti vitellinas Product name:

23D11-B04-232301 / 10 G Batch number / Weight:

BP VI Analysed according to:

Number of analysis / Inspection Code 23D11-B04 / INS-23-3381

V00764 / V23-0045 Reference Code / No.:

Tests	Requirement	Result	Unit	Standard remark
Appearance	Brown-black powder or pieces	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Conform	Conform		
Alcalinity	Conform	3,15	ml	
Related substances	Conform	Conform		
Chlorides	<=1,0	<1,0	%	
Free silver	Conform	Conform		
Loss on drying	<=8,0	2,43	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Silver	18,5 - 23,0	22,87	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release: Agnieszka Pszczółka Qualified Person

23-10-2023

Expiration: 06-10-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.